UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,363	01/27/2004	Richard J. Gregory	016930-005400US	2971

20350 7590 02/10/2005

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
GUZO, DAVID	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 02/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/766,363	GREGORY ET AL.	
	Examiner	Art Unit	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/30/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Abstract

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a **single paragraph** on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it is in two paragraphs. Correction is required. See MPEP § 608.01(b).

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The Declaration claims priority to application 08/233,777, filed 5/19/94, while the Continuing Data and the Application Data Sheet do not claim priority to this application. Indeed, in a preliminary amendment filed 1/27/04, applicants deleted

the priority claim for the 08/233,777 application and substituted a claim to the 08/246,006 application.

35 USC 102 Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 32-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Zhang et al. (US Patent 6,511,847, cited by applicants).

Applicants claim a DNA segment comprising an adenoviral ITR and a p53 coding region, the coding region positioned under the control of a CMV promoter and further comprising a polyA signal 3' to the p53 coding region and a E1 enhancer in the context of an adenoviral expression vector comprising E2 and E4 adenoviral genes and wherein the DNA is packaged in an adenovirus. Applicants have copied the instant claims from the 6,511,847 patent (to Zhang et al.) in order to preserve their rights under 35 USC 135(b).

Zhang et al. (priority to 10/29/93) recite the same claims as in the instant application. Specifically, the instant claims correspond to claims 1-5, 7, 9-10, 12 and 13 of the Zhang et al. patent. Applicants claim priority for the claimed

invention back to the filing date of the 08/142,669 (filed 10/25/93, hereafter the '669 application) application. Applicants however, do not have support for the claimed invention in the '669 application. Specifically, the '669 application does not disclose or suggest a DNA segment or adenoviral vector comprising a CMV promoter operably linked to a p53 coding region. The '669 application does not provide support for **any** DNA segment comprising an adenoviral ITR and a p53 coding region positioned under control of a CMV promoter packaged in an adenovirus. The '669 application provides support only for an adenoviral vector packaged in an adenovirus. Support for the claimed invention can be initially found in the 08/246,006 application (filed 5/19/94). Zhang et al. therefore is 102(e) art against the claimed invention.

Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 32-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-7, 9, 15, 17-20, 22, 24-25 of U.S. Patent No. 6,210,939 (hereafter the '939 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite DNAs encoding adenoviral expression vectors capable of expressing p53 under the control of a CMV promoter. While the claims in the '939 patent recite adenoviral expression vectors, it is noted that said expression vectors are DNA vectors since adenovirus is a DNA virus. With regard to the presence of the E1 enhancer in the vector (instant claim 36), it is noted that the claims of the '939 patent retain nucleotides 1 to 357 or 360 of the left end of the adenoviral genome, said region contains the E1 enhancer element. With regard to instant claim 41, the packaging of the adenoviral expression vector in an adenovirus would have been obvious since the adenovirus is a necessary carrier which delivers the vector to the target cells. It is also noted that the A/C/N/53 vector claimed in the '939 patent contains a left and right adenoviral ITR, E1 enhancer, a CMV promoter operably linked to a p53 coding sequence and a polyadenylation signal 3' of the p53 sequence as well as the adenoviral E2 and E4 genes.

Claims 32-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7, 9, 11-12, 16 and 18 of U.S. Patent No. 5,932,210 (hereafter the '210 patent). Although the conflicting claims are not identical, they are not patentably distinct from each

other because both sets of claims recite DNAs encoding adenoviral expression vectors capable of expressing p53 under the control of a CMV promoter. While the claims in the '210 patent recite adenoviral expression vectors, it is noted that said expression vectors are DNA vectors since adenovirus is a DNA virus. With regard to the presence of the E1 enhancer in the vector (instant claim 36), it is noted that the A/C/N/53 vector claimed in the '210 patent retains the E1 enhancer element upstream of the CMV-p53 expression cassette as well as the adenoviral E2 and E4 genes. With regard to instant claim 41, the packaging of the adenoviral expression vector in an adenovirus would have been obvious since the adenovirus is a necessary carrier which delivers the vector to the target cells. It is also noted that the A/C/N/53 vector claimed in the '210 patent contains a left and right adenoviral ITR, a CMV promoter operably linked to a p53 coding sequence and a polyadenylation signal 3' of the p53 sequence.

Claims 32-41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 32-41 of copending Application No. 10/602,258 (hereafter the '258 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because the recombinant adenoviruses claimed in the '258 application contain the instantly claimed DNA segments and expression vectors. With regard to the instantly claimed limitations concerning the presence of adenoviral ITRs, the E1 enhancer, and adenoviral E2 and E4 genes, an examination of the specification of the '258 application indicates that the only

disclosed adenoviral vectors comprise all these limitations and hence said limitations would be obvious over the claims in the '258 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
February 5, 2005

DAVID GUZO
PRIMARY EXAMINER